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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/548,310

08/16/2006

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

04/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/548,310	Applicant(s) LEE ET AL.	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/5/06; 10/16/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/5/06 and 10/16/06 are acknowledged and has been reviewed. Item #5 of IDS dated 12/5/06 is not considered because it is not a published document.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for lung cancer, uterine cancer and breast cancer does not reasonably provide enablement for a wide variation of cancers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2nd 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those

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in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

Nature of the Invention: All of the rejected claims are drawn to a composition for Cancer treatment which comprising a compound represented by formula 1. Wherein the compound of formula (I) has wide variation of substituents. The nature of the invention is extremely complex in that this compound of formula 1 is a composition for treatment of a wide variation of cancers.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass using of compound of formula (1) in the treatment of a very wide variation of cancers. For example as evident by ptcl.chem.ox.ac.uk/MSDS structure activity relationship should be considered because not every moiety or substituent recited would show potency upon their biological activity to the large variation of cancer encompassed by the claims. Note that the claim recite substituted and unsubstituted C(1-20).

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the compound being effective for treating a wide variation of cancers is missing. Cecil Text book of Medicine teaches that each specific type of cancer has a unique biologic and chemical features that must be appreciated for proper treatment (see page 1004). Therefore one skilled in the art would not have expected that the

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composition comprising compound of formula 1 would result in the treatment of a wide variation of cancers.

The Examiner acknowledges that the Office does not require the presence of working examples in the disclosure; however, given the highly unpredictable state of the art and that Applicant does not provide sufficient guidance or direction as to how to use this composition for the treatment of cancer the presently claimed invention without undue amount of experimentation, the Office would reasonably require further appropriate disclosure, possibly via examples commensurate with the scope of the present claims.

Claim Rejections - 35 USC § 102

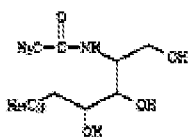
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Jackson et al., US 5578641.

The reference teaches with regards to instant claims 1 and 4 a composition comprising



wherein R¹ is ethanoyl or hydrogen. Ethanoyl as understood by the

examiner is a functional group with chemical formula –COCH₃ (absent factual

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evidence) as required by instant claims 1-2 and 4-5. See col. 5, lines 19-25. Examiner has interpreted the instant claims as being drawn to compositions comprising a compound as shown as an active ingredient. Applicants are reminded that intended use is not given patentable weight in claims drawn to compositions as required by instant claims 1 and 4. The Preambles of the instant claims recite intended uses, e.g. "An anti-cancer composition..." (Claim 1); "enhancement of radiosensitizing effect..." (Claim 4); are viewed as non-limiting since they do not recite essential steps "necessary to give life, meaning and vitality" to the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al., US 5578641 in view of Crossman et al. J. Biol. Chem, Vol. 252 (16) 5815-5819, 1977.

The above rejection is applied here as above.

Crossman et al teaches c18-phytosphingosine to have a NH₂. Thus having two hydrogens, obvious that R 1 is hydrogen. See highlighted sec of page 2

With regards to instant claims 3 and 6 one of ordinary skill in the art would have been motivated to have other substituents at the claimed position because at that position R1 has been represented to be either H. See col. 3, lines 40-65. It is noted that the example used in the reference at col. 3, lines 45-66 contains only 2 hydroxy groups. However, because R 1 can be hydrogen, one of ordinary skill in the art would be motivated to have hydrogen at that position from basic chemistry since it is obvious to easily form a NH₂. As stated the rate of formation is enhanced by these precursors. Thus it is within the level of one of ordinary skill in the art to use precursors that will enhance the formation of ceramide. See col. 3, lines 40-44.

One of ordinary skill in the art would have been motivated to combine the cited prior art together with basic knowledge in chemistry and have R1 to be hydrogen because Crossman teaches that H at that position.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614